

**IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF GEORGIA**

CONCORDIA PHARMACEUTICALS
INC., S.À.R.L., CONCORDIA
PHARMACEUTICALS (US) INC.,
and ADVANZ PHARMA CORP.,
Plaintiffs,

v.

WINDER LABORATORIES, LLC,
and STEVEN PRESSMAN,
Defendants.

WINDER LABORATORIES, LLC,
and STEVEN PRESSMAN,
Counterclaim Plaintiffs,

v.

CONCORDIA PHARMACEUTICALS
INC., S.À.R.L., CONCORDIA
PHARMACEUTICALS (US) INC.,
and ADVANZ PHARMA CORP.,
Counterclaim Defendants.

Civil Action No. 2:16-cv-00004-RWS

JURY TRIAL DEMANDED

ATTACHMENT C
COUNTERCLAIM DEFENDANTS'
OUTLINE OF THE CASE

ATTACHMENT C

COUNTERCLAIM PLAINTIFFS' OUTLINE OF THE CASE

I. Factual Summary

In 2015, Counterclaim Plaintiff Winder Laboratories, LLC (“Winder”) began to manufacture a phenobarbital-belladonna alkaloid (“PBA”) pharmaceutical product (“PBA Product(s)”) which would introduce into the PBA market a pharmaceutically equivalent, lower-cost alternative to Donnatal. By December 2015, Winder had launched its B-Donna PBA Product.

Counterclaim Defendant Concordia Pharmaceuticals, Inc., S.A.R.L. acquired Donnatal in 2014, and, along with Concordia Pharmaceuticals (US), Inc., and Advanz Pharma Corp. (collectively, “Concordia”) have aggressively attempted to preserve what they perceive to be Donnatal’s *de facto* monopoly in the PBA market. Once launched, competition from Winder’s PBA Products, which are “identical, related, or similar” to Donnatal’s PBA products, threatened to undermine Concordia’s ability to recoup the \$300 million acquisition cost of Donnatal.

Concordia initiated a multi-pronged attack designed to keep Winder’s PBA Product from entering the market. Concordia attempted to force the delisting of Winder’s products through threatening letters and unsuccessful litigation aimed at third-party drug databases. After discovering that the databases sought guidance from the FDA, Concordia lobbied the FDA in hopes of securing a declaration that Winder’s products were illegal and could not be marketed. The FDA instead determined that both Winder’s PBA products as well as Donnatal could remain on the market pending the determination of Donnatal’s DESI proceeding.

Beginning in January of 2016, Concordia and its agents, including lawyers at Buchanan Ingersoll & Rooney PC, communicated falsehoods about Winder's PBA Products through numerous letters, emails and other communications (the "Letters") to potential purchasers of Winder's products, including to retail pharmacies, drug wholesalers, and purchasing agents across the country. In the Letters, Concordia knowingly and falsely characterized the listings of Winder's PBA Products on third-party databases as "inaccurate and inappropriate." Concordia also made baseless claims about the safety of Winder's products and threatened that stocking Winder's products would expose these entities to civil and criminal liability. Some Letters explicitly declared Winder's PBA Products "illegal," "unlawful," or in a materially different regulatory state than Donnatal. But, such allegations were squarely contradicted by the FDA, which is the regulatory body charged with making such determinations.

Concordia papered the *entire PBA market*, sending round after round of Letters to Winder's potential purchasers, and directed their sales team to do whatever it took to make the letters "stick." These Letters were specifically designed to block purchases of Winder's PBA Products and to retain or otherwise secure Donnatal sales. As a result of the falsehoods in the Letters, Winder's potential customers canceled existing purchase agreements with Winder or declined to enter into agreements for Winder's PBA Products. Winder's PBA Product went unsold and Winder's efforts to bring a lower cost alternative into the market to compete with Donnatal were consequently delayed. As a result, Winder lost the market share it would have otherwise obtained. Specifically, Winder would have gained approximately 70% market share in one month; 82% in six months; and as high as 95% in its first 12 months.

Instead, because of Concordia's coordinated campaign of sending misleading letters to Winder's biggest potential customers, Winder's PBA Product only gained a total of 4% market share in 2016. With an understanding of how Phenohydro should have performed but for Concordia's interference, it is relatively straightforward to calculate Winder's lost profits. After calculating all costs and accounting for incremental revenue Winder's lost profits were \$32 million¹ as a result of Concordia's misrepresentations.

On January 1, 2016, Concordia filed a lawsuit against Winder Laboratories and Steven Pressman with this Court, alleging false advertising, tortious interference, and other related federal and state law claims. On March 29, 2017, Winder and Steven Pressman answered that complaint and included counterclaims of their own claiming damages arising from Concordia's activities described above. On February, 18, 2021, after a thorough review of all available facts and argument presented by both parties, summary judgment was entered in favor of Mr. Pressman and Winder dismissing all of Concordia's claims. Winder's counterclaims remain.

Winder's central allegations are that Concordia made misrepresentations in the Letter writing campaign to Winder's primary potential customers. Those Letters included several misrepresentations, but primarily asserted that Winder was marketing "illegal drug products under the name Phenohydro, which Winder claims are generic versions" of Donnatal. The effect of the summary judgment order in favor of Winder established that Concordia failed to provide any material evidence that Winder made false or misleading statements concerning the legality

¹ Winder's total lost profit damages equaled \$35.5 million, as of February 9, 2018, when including prejudgment interest at 7%. That number continues to increase, as prejudgment interest accrues until entry of any potential judgment against Concordia in this case.

of Phenohydro or its status as a “generic.” The Court’s order on summary judgment has now become law of the case, severely limiting most of Concordia’s reasonable defenses.

II. Rules, Regulations, Statutes, and Illustrative Cases Relied Upon by Plaintiffs

a. Statutes

- Section 34 of the Lanham Act, 15 U.S.C. § 1116.
- Section 35 of the Lanham Act, 15 U.S.C. § 1117(a)
- Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B)
- Food, Drug & Cosmetic Act, 21 U.S.C. § 301 *et seq.*
- Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-372
- Georgia Uniform Deceptive Trade Practices Act, O.C.G.A. § 10-1-373
- 28 U.S.C. 1961
- 21 U.S.C. § 352(e)
- 21 U.S.C. §§ 355(a), (j)(2)(A)(iv)
- 28 U.S.C. §§ 2201, 2202
- 52 Stat. 1040 § 505(b)(1)
- Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780

b. Regulations

- 21 CFR §§ 201.10, 201.51(a)
- 21 CFR § 310(a)
- 21 CFR § 310.6
- 210 CFR § 314.94(a)(3)
- 32 CFR § 314.3(b)
- 40 Fed. Reg. 52,644, 52,646 (1975)
- 48 Fed. Reg. 20,495, 20,501 (May 6, 1983)
- DESI 597, “Certain Drugs Containing an Anticholinergic with a Barbiturate.”

c. Illustrative Law

- *Biotics v. Heckler*, 710 F.2d 1375 (9th Cir 1983).
- *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 311 (1st Cir. 2002).
- *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics GmbH*, 2018 WL 4253181 (S.D. N.Y. 2018).
- *City of Pontiac Gen. Employees’ Ret. Sys. v. Stryker Corp.*, 865 F. Supp. 2d 811 (W.D. Mich. 2012).
- *Cody Laboratories, Inc. v. Sebelius*, 2010 WL 3119279 (D. Wyo. July 26, 2010), *aff’d in pertinent part*, 446 F. Appx. 964 (10th Cir. 2011).
- *Concordia Pharm., Inc. v. Method Pharm., LLC*, 240 F. Supp. 3d 449 (W.D. Va. 2017)

- *Craig v. Twinings, Inc.*, 2015 WL 505867 (W.D. Ark. Feb. 5, 2015)
- *Crossfit, Inc. v. Quinnie*, 232 F. Supp. 3d 1295 (N.D. Ga. Feb. 8, 2017)
- *Culpepper v. Thompson*, 562 S.E.2d 837 (Ga. Ct. App. 2002)
- *Davis v. S. Exposition Mgmt. Co.*, 232 Ga. App. 773 (1998)
- *Ford v. 1280 West Condo. Ass'n*, 2014 U.S. Dist. LEXIS 121792 (N.D. Ga. Sept. 2, 2014)
- *GPI Int'l Ltd. v. IBC Creative LLC*, No. 1:07-CV-1540-ODE, 2009 WL 10671357 (N.D. Ga. Sept. 16, 2009), *aff'd*, 396 F. App'x 661 (11th Cir. 2010)
- *Graceway Pharm., LLC v. River's Edge Pharm., LLC*, 2009 WL 3753586 (N.D. Ga. Nov. 6, 2009)
- *Hayes v. Irwin*, 541 F. Supp. 397 (N.D. Ga. 1982)
- *Hi-Tech Pharms., Inc. v. Hodges Consulting, Inc.*, 230 F.Supp.3d 132 (N.D. Ga. 2016)
- *In re Digitek Products Liability Litigation*, 821 F. Supp.2d 822, 834 (S.D.W. Va. 2011)
- *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242 (11th Cir. 2002)
- *Kason Indus., Inc. v. Component Hardware Grp., Inc.*, 120 F.3d 1199 (11th Cir. 2007).
- *Kirkland v. Tamplin*, 645 S.E.2d 653, 655-56 (Ga. Ct. App. 2007) (Georgia law elements of tortious interference)
- *Maurer Rides USA, Inc. v. Beijing Shibaolia Amusement Equip. Co.*, 2012 BL 426545 (M.D. Fla. May 30, 2012)
- *Merial LLC v. FidoPharm, Inc.*, 2014 U.S. Dist. LEXIS 199682 (N.D. Ga. September 5, 2014)
- *McDermott v. Middle E. Carpet Co., Associated*, 811 F.2d 1422 (11th Cir. 1987)
- *McGuire v. Dendreon Corp*, 2008 US Dist. Lexis 65436 (W.D. Wash. Apr. 18, 2008)
- *Meadow Springs, LLC. IH Riverdale*, 747 S.E.2d 47 (Ga. Ct. App. 2013)
- *Octane Fitness, LLC. v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1756 (2014)
- *Optimum Techs., Inc. v. Henkel Consumer Adhesives, Inc.*, 496 F.3d 1231 (11th Cir. 2007)
- *Optimum Tech., Inc. v. Home Depot USA, Inc.*, 2005 WL 3307508 (N.D. Ga. Dec. 5, 2005)
- *Osmose, Inc. v. Viance, LLC*, 612 F. 3d 1298 (11th Cir. 2010)
- *Pergo (Eur.) A.B. v. Stanley Black & Decker, Inc.*, No. 4:16-CV-319-HLM, 2018 WL 3949746 (N.D. Ga. May 7, 2018)
- *Phx. of Broward, Inc. v. McDonald's Corp.*, 441 F. Supp. 2d 1241 (N.D. Ga. 2006)
- *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2238 (2014)
- *Professionals & Patients for Customized Care v. Shalala*, 847 F. Supp. 1359 (S.D. Tex. 1994)
- *Ranbaxy Labs. Inc. v. First Databank, Inc.*, 826 F.3d 1334 (11th Cir. 2016)
- *Rowell v. Phoebe Putney Mem'l Hosp., Inc.*, 791 S.E.2d 183 (Ga. Ct. App. 2016)
- *Steifel Lab., Inc. v. Brookstone Pharm., L.L.C.*, 2012 WL 12888436 (N.D. Ga. July 24, 2012)

- *Schütz Container Sys., Inc. v. Mauser Corp.*, No. 1:09-CV-3609-RWS, 2012 U.S. Dist. LEXIS 44012 (N.D. Ga. Mar. 28, 2012)
- *Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F.Supp.2d 1293 (N.D. Ga. 2008)
- *U.S. Pharm. Corp. v. Trigen Labs.*, 2011 WL 446148 (N.D. Ga. Jan. 27, 2011)
- *Unique Sports Prod., Inc. v. Wilson Sporting Goods Co.*, 512 F. Supp. 1318 (N.D. Ga. 2007)
- *Wika Instrument I, LP v. Ashcroft, Inc.*, 2015 WL 11199059 (N.D. Ga. July 10, 2015)

d. Other Authorities

- OFFICE OF GENERIC DRUG POL’Y, U.S. FOOD & DRUG ASS’N, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (41st ed. 2021) (the “Orange Book”)
- CTR. FOR DRUG EVAL. & RES., U.S. FOOD & DRUG ADMIN., COMPLIANCE POLICY GUIDE 440.100: MARKETED NEW DRUGS WITHOUT APPROVED NDAs OR ANDAs (2011)

III. Damages

As a result of Concordia’s malfeasance, Winder seeks the following relief:

1. An order permanently enjoining Concordia from using false and misleading descriptions and representations of fact in commercial advertising and promotion about the nature, characteristics, and qualities of Winder’s products and from interfering with Winder’s contractual and business relationships. This injunctive relief is available pursuant to 15 U.S.C. § 1116 and O.C.G.A. § 10-1-373.
2. Compensatory damages for lost profits in an amount no less than \$32 million plus any prejudgment interest due at the date of entry of judgment pursuant to 15 U.S.C. § 1117(a) and 28 U.S.C. 1961.
3. Corrective advertising. This injunctive relief is available pursuant to 15 U.S.C. § 1116 and O.C.G.A. § 10-1-373.
4. Enhanced damages, including, but not limited to, an award of treble damages under 15 U.S.C. § 1117(a).
5. Reasonable attorneys’ fees, in recognition of this as an “exceptional case” pursuant to 15 U.S.C. § 1117(a) or, alternatively, in recognition of the willfulness of Concordia’s actions under O.C.G.A. § 10-1-373.
6. Punitive damages for Concordia’s tortious interference with Winder’s contractual relationships and potential business relationships. *Davis v. S. Exposition Mgmt. Co.*, 232 Ga. App. 773, 776 (1998) (“Tortious interference with business or contract may justify an award of punitives.”).

7. Any other relief as the Court deems just and proper.